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§12–504.

(a) In this section, "brand name" means the proprietary name a manufacturer places on a drug or device product or its container.

(b) (1) Subject to the provisions of this subtitle, a pharmacist, or the pharmacist's designee, who is under the direct supervision of the pharmacist, shall inform a retail consumer to the best of the pharmacist's or the pharmacist's designee's knowledge of the availability of a generically equivalent drug, a therapeutically equivalent brand name drug that is the lowest–cost alternative to the originally prescribed generically equivalent drug, or an interchangeable biological product and shall inform a retail consumer of the approximate cost difference of the lowest–cost alternative as compared to the originally prescribed drug.

(2) The Board shall adopt procedures for:

(i) A consumer to notify the Board when a pharmacist fails to provide the information required under paragraph (1) of this subsection; and

(ii) Advising a pharmacist to bring the pharmacist into compliance with the requirements of paragraph (1) of this subsection.

(3) Paragraph (1) of this subsection does not apply:

(i) When the authorized prescriber states expressly that the prescription is to be dispensed only as directed;

(ii) To a pharmacist who works in a pharmacy, whether centralized or decentralized, which primarily serves public or private institutional recipients; or

(iii) When the cost of the prescription is reimbursed by a third party payer, including medical assistance.

(c) The Board shall maintain a link on its website to the current lists of biological products determined by the United States Food and Drug Administration to be interchangeable with a specific biological product.

(d) (1) A pharmacist may substitute a generically equivalent drug or device product, a therapeutically equivalent brand name drug or device product to

the originally prescribed generically equivalent drug or device product, or an interchangeable biological product, of the same dosage form and strength, for the drug or device product originally prescribed, if:

(i) The authorized prescriber does not state expressly that the prescription is to be dispensed only as directed;

(ii) The substitution is:

1. Recognized in the United States Food and Drug Administration's current list of approved drug or device products with therapeutic equivalence evaluations; or

2. An interchangeable biological product for the drug or device product originally prescribed; and

(iii) The consumer is charged less for the substituted drug or device or interchangeable biological product than the price of the originally prescribed drug or device.

(2) If a retail consumer is using prescription drug coverage for the prescription, the determination of whether the consumer would be charged less for the substituted drug or device or interchangeable biological product shall be based on the consumer's prescription drug benefit and formulary, if that information is readily available.

(e) If a drug or device product or an interchangeable biological product is substituted under this section, the pharmacist shall:

(1) Notify the patient in writing, or maintain a record that indicates the patient has been notified in writing or orally, that the drug or device product or interchangeable biological product dispensed is a generic equivalent of, a brand name drug or device product that is therapeutically equivalent to, or is interchangeable with the originally prescribed drug or device product; and

(2) Record on the prescription and keep a record of the name and manufacturer of the substituted drug or device product or interchangeable biological product.

(f) The Department may list any additional drug or device products that are determined by the Department to meet requirements that are adequate to assure product quality and therapeutic equivalence, after an opportunity for public comment as provided in Title 10, Subtitle 1 of the State Government Article.

(g) The Department may disqualify a drug or device product or an interchangeable biological product on the United States Food and Drug Administration's current list from being used in Maryland as a substitute if the Department determines that the drug or device or interchangeable biological product is therapeutically nonequivalent or not interchangeable, respectively, or has a negative physical or biological effect on the consumer of that drug or device product or interchangeable biological product:

(1) After providing an opportunity for public comment as provided in Title 10, Subtitle 1 of the State Government Article; or

(2) Prior to providing an opportunity for public comment, if the Department believes that a particular generic drug or device product or interchangeable biological product constitutes an imminent danger to the public health, safety or welfare, and the Department:

(i) Provides an opportunity for public comment as provided in Title 10, Subtitle 1 of the State Government Article within 30 days of disqualifying the drug or device product or interchangeable biological product; and

(ii) After providing an opportunity for public comment, determines whether the drug or device product or interchangeable biological product should remain disqualified.

(h) For a drug or device product or an interchangeable biological product that the Department has disqualified from being used in Maryland as a substitute under subsection (g) of this section, the Department shall provide an opportunity for public comment as provided in Title 10, Subtitle 1 of the State Government Article before reinstating the drug or device product or interchangeable biological product for use in Maryland as a substitute.

(i) A pharmacist who substitutes a drug or device product or an interchangeable biological product in compliance with this section incurs no greater liability in filling the prescription by dispensing the equivalent drug or device product or interchangeable biological product than would be incurred in filling the prescription by dispensing the originally prescribed drug or device.

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